K132687 Page 10f2

510(k) E-CUBE 7

Section F 510(k) Summary

In accordance with 21CFR807.92, the following summary of information is provided;

Date Aug 26th 2013

Submitter: ALPINION MEDICAL SYSTEMS Co., Ltd.

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QARA Manager

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NOV 2 7 2013

Device Trade Name: E-CUBE 7

Common/Usual Name: Ultrasonic Pulsed Doppler Imaging System

<u>Classification Names</u> System, Imaging, Pulsed Doppler Ultrasonic

Product Code: Ultrasonic Pulsed Doppler Imaging System, 21CFR 892.1550 90-

IYN

Ultrasonic Pulsed Echo Imaging System, 21CFR 892.1560, 90-IYO Diagnostic Ultrasound Transducer, 21CFR 892.1570, 90-ITX

Predicate Device(s) K120060 E-CUBE 9 Diagnostic Ultrasound System

<u>Device Description:</u> E-CUBE 7 product is an ultrasound imaging system for medical

diagnosis. The system platform provides optimal patient diagnosis workflow with the 18.5" wide flat panel display, ergonomic control

panel with easy user interface, optimal image quality.

Indications For Use: The device is intended for use by a qualified physician for the

evaluation of soft tissue and blood flow in the clinical applications; Fetal; Abdominal (renal & GYN/pelvic); Pediatric; Small Organ (breast, testes, thyroid); Trans-rectal(TR); Trans-vaginal(TV); Musculo-skeletal (Conventional); Musculo-skeletal (Superficial); Cardiac (adult & pediatric); Peripheral Vascular (PV); and Urology

(including prostate).

Technology: E-CUBE 7 employs the same fundamental scientific technology as its predicate device.

Determination of Substantial Equivalence:

Summary of Non-Clinical Tests:

E-CUBE 7 has been evaluated for biocompatibility, acoustic output as well as thermal, electrical, electromagnetic, and mechanical safety, and has been found to conform to applicable medical device safety standards. E-CUBE 7 and its application comply with voluntary standards as detailed in this premarket submission. The following quality management system measures were applied to the development of E-CUBE 7:

- Medical Device Risk Management
- Requirements Reviews
- Design Reviews
- Component Verification
- Integration Review (System Verification)
- Performance Testing (System Verification)
- Safety Testing (Compliance Test)
- Design Validation

Transducer materials and other patient contact materials are biocompatible.

Summary of Clinical Tests:

The subject of this premarket submission, E-CUBE 7, did not require clinical studies to support substantial equivalence.

Conclusion:

ALPINION MEDICAL SYSTEMS Co., Ltd. considers E-CUBE 7 to be as safe, as effective. Performance, technology and software are substantially equivalent to the predicate device.

• The discussion about the technological and software differences between E-CUBE 7 and the predicate device: Some image parameters are added for operational convenience which means these parameters do not affect to the measurement accuracy. So there is no significant difference in essential performance, safety and effectiveness with the predicate device and the image parameter functions do not change the intended use.

ALPINION MEDICAL SYSTEMS Co., Ltd. will update and include in this summary any other information deemed reasonably necessary by the FDA or the requirements will be published in guidance documents.

DEPARTMENT OF HEALTH & HUMAN SERVICES





Food and Drug Administration 10903 New Hampshire Avenue Document Control Center – WO66-G609 Silver Spring, MD 20993-0002

November 27, 2013

Alpinion.Medical Systems Co., Ltd. % Mr. Donghwan Kim QARA Manager 1, 6 and 7FL Verdi Tower 72 Digital-ro(St) 26-gil(Rd) Guro-gu, Seoul 152-848 REPUBLIC OF KOREA

Re: K132687

Trade/Device Name: E-cube 7

Regulation Number: 21 CFR 892.1550

Regulation Name: Ultrasonic pulsed doppler imaging system

Regulatory Class: 11

Product Code: IYN, IYO, ITX Dated: August 26, 2013 Received: September 4, 2013

Dear Mr. Kim:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

This determination of substantial equivalence applies to the following transducers intended for use with the E-cube 7, as described in your premarket notification:

<u>Trans</u>	ducer Model Number	
C1-6	1.3-12	SP1-5
EN3-10	E3-10	VC1-6
1.3-8	SC1-6	1.3-12H
SP3-8	C5-8	1.3-1211 ^{WD}
103-12	L8-17	CW 2.0
CW5.0	EV3-10	EC3-10

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safetv/ReportaProblem/default.htm for the CDRH's Office

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

of Surveillance and Biometrics/Division of Postmarket Surveillance.

Sincerely yours,

Janine M. Morris

Smh. 7)

Director, Division of Radiological Health

for

Office of In Vitro Diagnostics

and Radiological Health

Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K132687

Section E Indications for Use Statement

Device Name: E-CUBE 7
Indications for Use:
The device is intended for use by a qualified physician for the evaluation of soft tissue and blood flow in the clinical applications; Fetal; Abdominal (renal & GYN/pelvic); Pediatric; Small Organ (breast, testes, thyroid); Trans-rectal(TR); Trans-vaginal(TV); Musculo-skeletal(Conventional); Musculo-skeletal (Superficial); Cardiac (adult&pediatric); Peripheral Vascular (PV); and Urology (including prostate).
Prescription Use AND/OR Over-The-Counter Use (Part 21 CFR 801 Subpart D) (Part 21 CFR 807 Subpart C) (PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)
Concurrence of CDRH, Office of In-Vitro Diagnostic Devices (OIVD) (Division Sign-Off) Division of Radiological Health Office of In Vitro Diagnostics and Radiological Health
510(k)K132687

K132687

E-CUBE 7 Ultrasound System

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation											
	В	M	PWD	CWD	Color Doppler	Power Doppler	Tissue Harmonic Imaging	Combined* (Specify)	Other** (Specify)			
Ophthalmic	1	\Box										
Fetal	P	Р	Р	1	Р	P	Р	Р	P			
Abdominal	P	P	Р	·	Р	Р	Р	Р	Р			
Intra-operative (Specify)	\top											
Intra-operative (Neuro)	1						<u> </u>					
Laparoscopic	 						_					
Pediatric	P	P	Р		Р	Р	Р	P	Р			
Small Organ (breast, testes, thyroid)	Р	Р	P		Р	P	Р	P				
Neonatal Cephalic	1						<u> </u>					
Adult Cephalic	1											
Trans-rectal	Р	Р	P		Р	þ	P	Р				
Trans-vaginal	P	Р	Р		P	Ь	Р	Р				
Trans-urethral												
Trans-esoph. (non-Card.)	1											
Musculo-skeletal (Conventional)	Р	Р	Ь		Р	Р	Р	P				
Musculo-skeletal (Superficial)	Р	Р	Р		Р	P	Р	Р				
Intravascular			·									
Cardiac Adult	P	Р	Р	N	Р	Р	Р	Р				
Cardiac Pediatric	P	Р	Р	N	Р	Р	Р	Р				
Intravescular (Cardiac)												
Trans-esoph. (Cardiac)	1											
Intra-cardiac	\top											
Peripheral vessel	P	Р	Р		Р	P	P	Р				
Uralogy (including prostate)	P	Р	Р		Р	P	Р	P	Р			

N = new indication; P = previously cleared by FDA K123811; E = added under appendix

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In-Vitro Diagnostic Devices (OIVD)

^{*} Combined: B/Color Doppler, B/PWD, B/Color Doppler/PWD; **Other: 3D, 4D

E-CUBE 7 with C1-6 Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation											
	В	M	PWD	CWD	Color Doppler	Power Doppler	Tissue Harmonic Imaging	Combined* (Specify)	Other** (Specify)			
Ophthatmic	\top											
Fetal	Р	P	·P		Р	Р	Р	Р				
Abdominal	P	P	Р		Р	Р	Р	Р				
Intra-operative (Specify)	1			1								
Intra-operative (Neuro)	1											
Laparoscopic	1											
Pediatric	P	Р	Р		Р	Р	Р	Р				
Small Organ	 				_							
(breast, testes, thyroid)						!						
Neonatal Cephalic	 											
Adult Cephalic	1	Г			- 	i						
Trans-rectal	1											
Trans-vaginal	1					·						
Trans-urethral	1	1										
Trans-esoph. (non-Card.)												
Musculo-skeletal	1											
(Conventional)												
Musculo-skeletal	1						_					
(Superficial)												
Intravascular	1											
Cardiac Adult	T-											
Cardiac Pediatric	1											
Intravascular (Cardiac)												
Trans-esoph. (Cardiac)	1											
Intra-cardiac												
Peripheral vessel												
Urology (including prostate)	Р	P	P		Р	Р	Р	Р				

N = new indication; P = previously cleared by FDA K121729; E = added under appendix

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In-Vitro Diagnostic Devices (OIVD)

^{*} Combined: B/Color Doppler, B/PWD, B/Color Doppler/PWD; **Other: 3D, 4D

E-CUBE 7 with L3-12 Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mo	de of	Operation)			<u></u>		
	В	M	PWD	CWD	Cotor	Power	Tissue	Combined*	Other*
		1			Doppler	Doppler	Harmonic	(Specify)	(Specify)
	↓						Imaging		
Ophthalmic	↓	Ш				ļ	ļ <u>.</u>		ļ
Fetal		Ш				ļ			<u> </u>
Abdominal	<u>l</u>					_			
Intra-operative (Specify)									[
Intra-operative (Neuro)									
Laparoscopic									
Pediatric	P	P	Р		P	Р	Р	Р	
Small Organ	P	Р	Р		Р	Р	Р	р	
(breast, testes, thyroid)	'		•		· ·	['	,	
Neonatal Cephalic									
Adult Cephalic									
Trans-rectal			·	-		-			
Trans-vaginal	† ·					<u> </u>		,	
Trans-urethral	1		-			† 			
Trans-esoph. (non-Card.)	1								
Musculo-skeletal	P	Р	P		P	Р	Р	Р	
(Conventional)			P		r			,]
Musculo-skeletal	P	P	Р		Р	P	Р	Р	
(Superficial)	-		r			'	['	,	}
Intravascular					- · · <u>-</u>				-
Cardiac Adult	1								
Cardiac Pediatric							l		
Intravascular (Cardiac)	t	М		_		<u> </u>	<u> </u>		
Trans-esoph. (Cardiac)	†	\Box				<u> </u>	<u> </u>		
Intra-cardiac	T					T			
Peripheral vessel	₽	P	P		P	Р	P	Р	-
Urology (including prostate)	1		-			<u> </u>			
				1/40470		 	n notice		

N = new indication; P = previously cleared by FDA K121729; E = added under appendix

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In-Vitro Diagnostic Devices (OIVD)

^{*} Combined: B/Color Doppler, B/PWD, B/Color Doppler/PWD; **Other: 3D, 4D

E-CUBE 7 with SP1-5 Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation											
	В	M	PWD	CWD	Color Doppler	Power Doppler	Tissue Harmonic Imaging	Combined* (Specify)	Other** (Specify)			
Ophthalmic	1					<u> </u>			ļ			
Fetal	1 -				_							
Abdominat	P	Р	₽		P	Р	P	Р	[
Intra-operative (Specify)	1			<u> </u>	-		•					
Intra-operative (Neuro)	1											
Laparoscopic	1					 						
Pediatric	P	Р	Р		P	P	Р	Р				
Small Organ	1			†——-		-			<u> </u>			
(breast, testes, thyroid)									l			
Neonatal Cephalic												
Adult Cephalic	1											
Trans-rectal	1											
Trans-vaginal	1		-									
Trans-urethral	 											
Trans-esoph. (non-Card.)	 											
Musculo-skelatal	1]			
(Conventional)									_			
Musculo-skeletal	-											
(Superficial)					ļ		l					
Intravascular												
Cardiac Adult	P	P	Ρ	N	Р	Р	Р	Ρ				
Cardiac Pediatric								/				
Intravascular (Cardiac)	1				_							
Trans-esoph. (Cardiac)	1											
Intra-cardiac	1											
Peripheral vessel	1	Π										
Urology (including prostate)	1											

N = new indication; P = previously cleared by FDA K121729; E = added under appendix

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In-Vitro Diagnostic Devices (OIVD)

^{*} Combined: B/Color Doppler, B/PWD, B/Color Doppler/PWD; **Other: 3D, 4D

E-CUBE 7 with EN3-10 Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation											
	В	M	PWD	CWD	Color Doppler	Power Doppler	Tissue Harmonic Imaging	Combined* (Specify)	Other* (Specify)			
Ophthalmic	-		· · · · ·				-					
Fetal	1	П		1								
Abdominal		П										
Intra-operative (Specify)												
Intra-operative (Neuro)			-									
Laparoscopic	\top											
Pediatric	1	H										
Small Organ	1	П					<u> </u>					
(breast, testes, thyroid)					<u> </u>]	ļ.		l			
Neonatal Caphalic	1											
Adult Cephalic	1.	П			_							
Trans-rectal	P	Р	Р		Р	Р	P	Ρ				
Trans-vaginal	Р	P	P		P	Р	Р	Р				
Trans-urethral	\top											
Trans-esoph. (non-Card.)	1		·					-				
Musculo-skeletal	1 -	\vdash	-									
(Conventional)												
Musculo-skeletal	1								1			
(Superficial)							<u> </u>					
Intravascular	1	1										
Cardiac Adult	1	abla		I								
Cardiac Pediatric												
Intravascular (Cardiac)	\top											
Trans-esoph. (Cardiac)	1											
Intra-cardiac	1											
Peripheral vessel	1		-									
Urology (including prostate)	P	P	P	<u> </u>	P	Р	P	P	<u> </u>			

N = new indication; P = previously cleared by FDA K121729; E = added under appendix

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In-Vitro Diagnostic Devices (OIVD)

Prescription User (Per 21 CFR 801.109)

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^{*} Combined: B/Color Doppler, B/PWD, B/Color Doppler/PWD; **Other: 3D, 4D

E-CUBE 7 with E3-10 Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation											
	В	M	PWD	CWD	Color Doppler	Power Doppler	Tissue Harmonic Imaging	Combined* (Specify)	Other** (Specify)			
Ophthalmic	†	П						Ì				
Fetal	1 -	П				,						
Abdominal			. –									
Intra-operative (Specify)	T											
Intra-operative (Neuro)												
Laparoscopic	1											
Pediatric												
Small Organ	†											
(breast, testes, thyroid)					ĺ							
Neonatal Cephalic	† _											
Adult Cephalic		П										
Trans-rectal	P	Р	Р		Р	Р		P				
Trans-vaginal	Р	P	P		Р	Р		P				
Trans-urethral												
Trans-esoph. (non-Card.)									İ			
Musculo-skeletal			_						T			
(Conventional)												
Musculo-skeletal	\top			1					1			
(Superficial)	1								<u> </u>			
Intravascular	1								<u> </u>			
Cerdiac Adult	1								<u></u>			
Cardiac Pediatric	1											
Intravascular (Cardiac)	\top	_										
Trans-esoph. (Cardiac)	1	ļ		1								
Intra-cardiac	† –			<u> </u>								
Peripheral vessel	\top	Π										
Urology (including prostate)	P	Р	P		Р	P		P				

N = new indication; P = previously cleared by FDA K121729; E = added under appendix

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In-Vitro Diagnostic Devices (OIVD)

Combined: B/Color Doppler, B/PWD, B/Color Doppler/PWD; **Other: 3D, 4D

E-CUBE 7 with VC1-6 Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation										
	В	M	PWD	CWD	Color Doppler	Power Doppler	Tissue Harmonic Imaging	Combined* (Specify)	Other** (Specify)		
Ophthalmic											
Fetal	Р	Р	P		Р	Р	Р	Р	Р		
Abdominal	P	Р	P		Р	Р	P	Р	Р		
Intra-operative (Specify)	1					-					
Intra-operative (Neuro)			-								
Laparoscopic	1										
Pediatric	Р	Р	Р		Р	Р	Р	Р	Р		
Small Organ	1					•					
(breast, testes, thyroid)								[
Neonatal Cephallc									Ĭ .		
Adult Cephalic	1										
Trans-rectal											
Trans-vaginal	1										
Trans-urethral	1										
Trans-esoph. (non-Card.)	1										
Musculo-skeletal	1				ľ						
(Conventional)	1								}		
Musculo-skeletal											
(Superficial)											
Intravascular	1										
Cardiac Adult	T										
Cardiac Pediatric											
Intravascular (Cardiac)											
Trans-esoph. (Cardiac)											
Intra-cardiac											
Peripheral vessel											
Urology (including prostate)	Р	Р	Р		Р	Р	Р	Ρ	N		

N = new indication; P = previously cleared by FDA K120060; E = added under appendix

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In-Vitro Diagnostic Devices (OIVD)

Prescription User (Per 21 CFR 801.109)

Page 008 of 020

^{*} Combined: B/Color Doppler, B/PWD, B/Color Doppler/PWD; **Other: 3D, 4D

E-CUBE 7 with L3-8 Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation											
	В	M	PWD	CWD	Color Doppler	Power Doppler	Tissue Harmonic Imaging	Combined* (Specify)	Other** (Specify)			
Ophthaimic	†											
Fetal	\top											
Abdominal	1	1										
Intra-operative (Specify)	1	П										
Intra-operative (Neuro)	1						· · · · · · · · · · · · · · · · · · ·					
Laparoscopic	1											
Pediatric	Р	Р	Р		ρ	Р	P.	Р				
Small Organ (breast, testes, thyroid)	Р	Р	P		Р	Р	P	Р				
Neonatal Caphalic	┿	 		 								
Adult Cephalic	+	Н										
Trans-rectal	1			 								
Trans-vaginal	1	-		 -					· · · · · · · · · · · · · · · · · · ·			
Trans-urethral	†											
Trans-esoph. (non-Card.)	1-					i						
Musculo-skeletal (Conventional)	Р	Р	Р		Р	Р	Р	Р				
Musculo-skeletal (Superficial)	Р	Р	Р		Р	Р	Р	Р				
Intravascular	†											
Cardiac Adult	1	П										
Cardiac Pediatric	1			l								
Intravascular (Cardiac)												
Trans-esoph. (Cardiac)		П		Ţ								
Intra-cardiac	1											
Peripheral vessel	Р	Р	Р		Р	þ	P	Ρ				
Urology (including prostate)	1											

N = new indication; P = previously cleared by FDA K120060; E = added under appendix

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In-Vitro Diagnostic Devices (OIVD)

^{*} Combined: B/Color Doppler, B/PWD, B/Color Doppler/PWD; **Other: 3D, 4D

E-CUBE 7 with SC1-6 Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation											
	8	M	PWD	CWD	Color	Power	Tissuo	Combined*	Other**			
				ļ	Dopplor	Dopplor	Harmonic	(Specify)	(Specify)			
							Imaging					
Ophthalmic												
Fetal	Р	Р	P		Р	Р	Р	Р				
Abdominal	Р	Р	Р		Р _	P	Р	Р				
Intra-operative (Specify)												
Intra-operative (Neuro)	Ι											
Laparoscopic												
Pediatric	Р	Р	P		P	P	P	Р				
Small Organ				·	[
(breast, testes, thyroid)												
Neonatal Cephalic												
Adult Cephalic			-						I			
Trans-rectal	1					Ī						
Trans-vaginal												
Trans-urethral	1											
Trans-esoph. (non-Card.)	1											
Musculo-skeletal	1											
(Conventional)									l			
Musculo-skeletal												
(Superficial)		l .			Ì							
Intravascular												
Cardiac Adult	1											
Cardiac Pediatric	1					ĺ						
Intravascular (Cardiac)						'						
Trans-esoph. (Cardiac)	1											
Intra-cardiac	1											
Peripheral vessel	1											
Urology (including prostate)	Р	P	P		Р	Р	Р	Р				

N = new indication; P = previously cleared by FDA K120060; E = added under appendix

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In-Vitro Diagnostic Devices (OIVD)

Prescription User (Per 21 CFR 801.109)

E-10

^{*} Combined: B/Color Doppler, B/PWD, B/Color Doppler/PWD; **Other: 3D, 4D

E-CUBE 7 with L3-12H Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation											
	В	M	PWD	CWD	Color Doppler	Power Doppler	Tissuo Harmonic Imaging	Combined' (Specify)	Other** (Specify)			
Ophlhalmic	1	П										
Fetal	1											
Abdominal	1						Î					
Intra-operative (Specify)		П				-						
Intra-operative (Neuro)		П			·	<u> </u>						
Laparoscopic	1	П					· · · · · · · · · · · · · · · · · · ·					
Pediatric	Р	Р	P ·		Р	Р	Р	P				
Small Organ (breast, testes, thyroid)	Р	Р	P		Р	Р	Р	Ρ				
Neonatal Cephalic	+	Н			•			-				
Adult Cephalic	┿╌	Н										
Trans-rectal	+	Н							-			
Trans-vaginal	+											
Trans-urethral	1	\square										
Trans-esoph. (non-Card.)									-			
Musculo-skeletal (Conventional)	Р	Р	<u></u> . Р		Р	P .	Р	Р				
Musculo-skeletal (Superficial)	Р	Р	Р		Р	· Р	Р ,	Ρ				
Intravascular	1											
Cardiac Adult		\Box						_				
Cardiac Pediatric	Ť											
Intravascular (Cardiac)	\top											
Trans-esoph. (Cardiac)	T^{-}	\Box	-									
Intra-cardiac	1								·			
Peripheral vessel	P	Р	P		Р	Р	P	Р				
Urology (including prestate)	1											

N = new indication; P = previously cleared by FDA K120060; E = added under appendix

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In-Vitro Diagnostic Devices (OIVD)

^{*} Combined: B/Color Doppler, B/PWD, B/Color Doppler/PWD; **Other: 3D, 4D

E-CUBE 7 with SP3-8 Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation										
	8	M	PWD	CWD	Color Doppler	Power Doppler	Tissuo Harmonic Imaging	Combined* (Specify)	Other** (Specify		
Ophthalmic	1	H					····				
Fetal		П									
Abdominal	P	Р	Р		Р	Р	Р	Р			
Intra-operative (Specify)	\top										
Intra-operative (Neuro)											
Laparoscopic											
Pediatric	Р	Р	Р		P	Р	P	Р			
Small Organ	1	П				<u> </u>		i			
(breast, testes, thyroid)								ļ			
Neonatal Cephalic	1										
Adult Cephalic	1								Ī		
Trans-rectal											
Trans-vaginal	1	M									
Trans-urethral	 										
Trans-esoph. (non-Card.)	\top										
Musculo-skeletal	\top			1			1				
(Conventional)									1		
Musculo-skeletal	1										
(Superficial)								l			
Intravascular	1										
Cardiac Adult	1	П						<u> </u>			
Cardiac Pediatric	Р	ρ	Р	Р	Р	Р	P.	Р			
Intravascular (Cardiac)	1										
Trans-esoph. (Cardiac)	1						Ì				
Intra-cardiac	1										
Peripheral vessel	┪										
Urology (including prestate)	1	П		1							

N = new Indication; P = previously cleared by FDA K120060; E = added under appendix

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Concurrence of CDRH, Office of In-Vitro Diagnostic Devices (OIVD)

^{*} Combined: B/Color Doppter, B/PWD, B/Color Doppler/PWD; **Other: 3D, 4D

E-CUBE 7 with C5-8 Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation											
	В	М	PWD	CWD	Color	Power	Tissue	Combined*	Other**			
					Doppler	Doppler	Harmonic	(Specify)	(Specify)			
	L		L				imaging					
Ophthalmic	Т											
Fetal												
Abdominal	N	N	N		N	N	N	N				
Intra-operative (Specify)							,		_			
Intra-operative (Neuro)	1											
Laparoscopic					_		"					
Pediatric	N	N	N		N	N	N	ν				
Small Organ	1		· · ·									
(breast, testes, thyroid)				,								
Neonatal Cephalic	\top				-							
Adult Cephalic												
Trans-rectal	1-						,		·· · ·			
Trans-vaginal	1											
Trans-urethral	†						-	,				
Trans-esoph. (non-Card.)		П										
Musculo-skeletal	1	П										
(Conventional)												
Musculo-skeletal	+-			- -	-							
(Superficial)												
Intravascular		П										
Cardiac Adult	1											
Cardiac Pediatric	N	N	N		N	N	N	N				
Intravascular (Cardiac)												
Trans-esoph. (Cardiac)	1											
Intra-cardiac		П					-					
Peripheral vessel	 											
Urology (including prostate)	 	\Box										

N = new indication; P = previously cleared by FDA; E = added under appendix

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Concurrence of CDRH, Office of In-Vitro Diagnostic Devices (OIVD)

^{*} Combined: B/Color Doppler, B/PWD, B/Color Doppler/PWD; **Other: 3D, 4D

E-CUBE 7 with L3-12HWD Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation											
	В	M	PWD	CWD	Color Doppler	Power Doppler	Tissue Harmonic Imaging	Combined*	Other** (Specify)			
Ophthalmic	1	П							i			
Fetal	1											
Abdominal	1	П					Ī					
Intra-operative (Specify)	 											
Intra-operative (Neuro)	†	т							···			
Laparoscopic	1 -											
Pediatric	1											
Small Organ (breast, testes, thyroid)	N	N	N		N	N		N				
Neonatal Cephalic	+	Н		· -			<u> </u>					
Adull Cephalic	1											
Trans-rectal	1								<u> </u>			
Trans-vaginal	1			-								
Trans-urethral	1	П										
Trans-esoph. (non-Card.)	1								<u> </u>			
Musculo-skeletal (Conventional)	N	N	N		N	N		N				
Musculo-skeletal (Superficial)	N	z	N		N	N		N				
Intravascular	\top											
Cardiac Adult												
Cardiac Pediatric												
Intravascular (Cardiac)	1	H		<u> </u>		<u> </u>						
Trans-esoph. (Cardiac)	\top	П										
Intra-cardiac	1 -		-									
Peripheral vessel	\top								٩			
Urology (including prostate)	1	П		1								

N = new indication; P = previously cleared by FDA; E = added under appendix

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Concurrence of CDRH, Office of In-Vitro Diagnostic Devices (OIVD)

^{*} Combined: B/Color Doppler, B/PWD, B/Color Doppler/PWD; **Other: 3D, 4D

E-CUBE 7 with IO3-12 Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation											
	В	M	PWD	CWD	Color Doppler	Power Doppler	Tissue Harmonic Imaging	Combined* (Specify)	Other** (Specify)			
Ophthalmic												
Fetal												
Abdominal												
Intra-operative (Specify)	 			 								
Intra-operative (Neuro)	1			<u> </u>								
Laparoscopic	T				i							
Pediatric		П										
Small Organ (breast, testes, thyroid)	N	N	N	_	N	N	. N	N				
Neonatal Cephalic	1											
Adult Cephalic		П										
Trans-rectal	-											
Trans-vaginal												
Trans-urethral												
Trans-esoph. (non-Card.)												
Musculo-sketetal (Conventional)												
Musculo-skeletal (Superficial)												
Intravascular									<u> </u>			
Cardiac Adult												
Cardiac Pediatric												
Intravascular (Cardiac)	T	I										
Trans-esoph. (Cardiac)												
Intra-cardiac												
Peripheral vessel												
Urology (including prostate)							l					

N = new indication; P = previously cleared by FOA; E = added under appendix

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Concurrence of CDRH, Office of In-Vitro Diagnostic Devices (OIVD)

Combined: B/Color Doppler, B/PWD, B/Color Doppler/PWD; **Other: 3D, 4D

E-CUBE 7 with L8-17 Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation											
	В	M	PWD	CWD	Color Doppler	Power Doppler	Tissue Harmonic Imaging	Combined*	Other** (Specify)			
Ophthalmic	+			 					 			
Felal	†	П							1			
Abdominal	†											
Intra-operative (Specify)	┼─	Н		 								
Intra-operative (Neuro)	 	-										
Laparoscopic	\dagger	Н		 			·		 			
Pediatric	l N	N	N		N	N	N	N	 			
Small Organ	N	N	N	1	N	N	N	N				
(breast, testes, thyroid)	"	"	N		14	N		, N				
Neonatal Cephalic												
Adult Cephalic	1-						,, 					
Trans-rectal		П										
Trans-vaginal	1											
Trans-urethral	1											
Trans-esoph. (non-Card.)	1	П										
Musculo-skeletal (Conventional)	N	N	N		N	N	N	N				
Musculo-skeletal (Superficial)	N	N	. N		N	N	N	N				
Intravascular	1											
Cardiac Adult	1	\dagger										
Cardiac Pediatric	1						<u> </u>					
Intravascular (Cardiac)	†	H	-									
Trans-esoph. (Cardiac)	†				·							
Intra-cerdiac	 											
Peripheral vessel	N	N	N		N	Ň	N ·	N				
Urology (including prostate)						_	<u></u> .					

N = new indication; P = previously cleared by FDA; E = added under appendix

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Concurrence of CDRH, Office of In-Vitro Diagnostic Devices (OIVD)

^{*} Combined: B/Color Doppler, B/PWD, B/Color Doppler/PWD; **Other: 3D, 4D

E-CUBE 7 with CW 2.0 Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation											
	В	M	PWD	CWD	Color Doppler	Power Doppler	Tissue Harmonic Imaging	Combined* (Specify)	Other* (Specify)			
Ophthalmic								-				
Fetal												
Abdominal												
Intra-operative (Specify)	\vdash	H										
Intra-operative (Neuro)	 											
Laparoscopic	T			<u> </u>								
Pediatric												
Small Organ (breast, testes, thyroid)	-			-								
Neonatal Cephalic	\vdash		-	 								
Adult Cephalic	 											
Trans-rectal	1	П				·						
Trans-vaginal	1	М					,					
Trans-urethral		П							,			
Trans-esoph. (non-Card.)	1	П					-					
Musculo-skeletal (Conventional)												
Musculo-skeletal (Superficial)												
Intravascular	1											
Cardiac Adult				Р								
Cardiac Pediatric				Р								
Intravascular (Cardiac)	\vdash	H										
Trans-esoph. (Cardiac)	\vdash	П										
Intra-cardiac	\top	П										
Peripheral vessel		П										
Urology (including prostate)												

N = new indication; P = previously cleared by FDA K123610; E = added under appendix

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Concurrence of CDRH, Office of In-Vitro Diagnostic Devices (OIVD)

^{*} Combined: B/Color Doppler, B/PWD, B/Color Doppler/PWD; **Other: 3D, 4D

E-CUBE 7 with CW5.0 Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation										
	В	M	PWD	CMD	Cotor Doppler	Power Doppler	Tissuo Harmonic Imaging	Combined* (Specify)	Other** (Specify)		
Ophthalmic						-					
Fetal						_					
Abdominal											
Intra-operative (Specify)	1										
Intra-operative (Neuro)						1					
Laparoscopic											
Pediatric	Î						1				
Small Organ (breast, testes, thyroid)											
Neonatal Cephalic	 										
Adult Cephalic	+	П			-						
Trans-rectal		\Box		1							
Trans-vaginal	1										
Trans-urethral		П									
Trans-esoph. (non-Card.)								·	<u> </u>		
Musculo-skeletal (Conventional)											
Musculo-skeletal (Superficial)											
Intravascular									<u></u>		
Cardiac Adult				Р							
Cardiac Pediatric				P					l		
Intravascular (Cardiac)	†	1		1		1					
Trans-esoph. (Cardiac)	1-	Π							<u> </u>		
Intra-cardiac	1										
Peripheral vessel	1.										
Urology (including prostate)		T							_ [

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^{*} Combined: B/Color Doppler, B/PWD, B/Color Doppler/PWD; **Other: 3D, 4D

E-CUBE 7 with EV3-10 Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation										
	В	M	PWD	CWD	Color_ Doppler	Power Doppler	Tissue Harmonic Imaging	Combined* (Specify)	Other** (Specify)		
Ophthalmic	1					i					
Fetal											
Abdominat	1						"				
Intra-operative (Specify)	+										
Intra-operative (Neuro)	1	П		 							
Laparoscopic		П						· · ·			
Pediatric	1										
Small Organ (breast, testes, thyroid)											
Neonatal Cephalic	<u> </u>	†									
Adult Cephalic		\Box			·		<u> </u>				
Trans-rectal	N	N	7	 	N	N		N			
Trans-vaginal	N	N	N		N	N		N			
Trans-urethral							,				
Trans-esoph. (non-Card.)											
Musculo-skeletai (Conventional)						-					
Musculo-skeletal (Superficial)											
Intravescular	1										
Cardiac Adult											
Cardiac Pediatric]				
Intravascular (Cardiac)	\top					<u> </u>					
Trans-esoph. (Cardiac)	\top										
Intra-cardiac	1										
Peripheral vessel	1	П									
Urology (including prostate)	Ň	7	N	{	N	N		N N			

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Concurrence of CDRH, Office of In-Vitro Diagnostic Devices (OIVD)

^{*} Combined: B/Color Doppler, B/PWD, B/Color Doppler/PWD; **Other: 3D, 4D

E-CUBE 7 with EC3-10 Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation										
	В	M	PWO	CWD	Color Doppler	Power Doppler	Tissue Hamnonic Imaging	Combined*	Other** (Specify)		
Ophthalmic	1		,								
Fetal	1										
Abdominal											
Intra-operative (Specify)	1	H									
Intra-operative (Neuro)	 										
Laparoscopic	†	П									
Pediatric	†-										
Small Organ	+			-				<u></u>			
(breast, testes, thyroid)	1				•						
Neonatal Cephalic	†						-				
Adult Cephalic	1-						-				
Trans-rectal	N	N	N		N	N	1	N	-		
Trans-vaginal	N	N	N		N	N		N ·			
Trans-urethral	\top										
Trans-esoph. (non-Card.)	1										
Musculo-skeletal							,				
(Conventional)		,		<u> </u>							
Musculo-skeletal											
(Suporficial)	⊥_				ļ						
Intravascular	<u> </u>										
Cardiac Adult	┷.				<u> </u>						
Cardiac Pediatric						_					
Intravascular (Cardiac)	L										
Trans-esoph. (Cardiac)											
Intre-cardiac											
Peripheral vessel								<u> </u>	ļ		
Urology (including prostate)	N	Z	2		N dad under a	N		N	<u> </u>		

N = new indication; P = previously cleared by FDA; E = added under appendix

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Concurrence of CDRH, Office of In-Vitro Diagnostic Devices (OIVD)

^{*} Combined: B/Color Doppler, B/PWD, B/Color Doppler/PWD; **Other: 3D, 4D